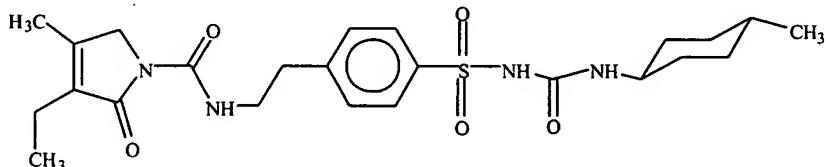


**We claim**

1) A process for the preparation of *trans*-3-Ethyl-2,5-dihydro-4-methyl-N-[2-[4-[[[[4-methylcyclohexyl]amino]carbonyl]amino]sulfonyl]phenyl]ethyl]-2-oxo-1*H*-pyrrole-1-carboxamide, a compound of the formula 1,

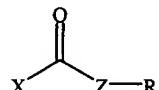


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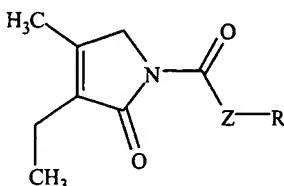
**Formula 1**

comprising,

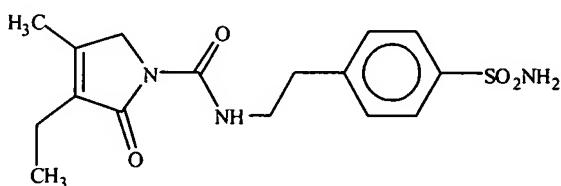
a) reacting 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2,

**Formula 2**

to obtain a compound of formula 3,

**Formula 3**

b) reacting a compound of formula 3 with 4-(2-Aminoethyl)benzene sulfonamide to obtain 4-[2-(3-Ethyl-4-methyl-2-carbonyl pyrrolidine amido)ethyl]benzene sulfonamide, a compound of formula 4,

**Formula 4**

c) and further reacting the compound of formula 4 with *trans*-4-methylcyclohexyl isocyanate to obtain the compound of formula 1,  
 wherein,

X is halogen, nitroaryl or haloaryl,

5 Z is O, S or NY, wherein Y is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>1</sub>-C<sub>5</sub><sup>1</sup>-haloalkyl, aryl or aralkyl, and R is aryl or heteroaryl, where aryl or heteroaryl radical is unsubstituted or substituted by one or more radicals from the group consisting of nitro, halogen, cyano, azido, haloalkyl, CO-R<sup>1</sup>, SR<sup>2</sup>, SO-R<sup>3</sup> and SO<sub>2</sub>-R<sup>4</sup>,

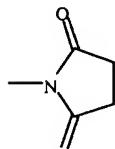
10 R<sup>1</sup> is H, C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-alkoxy or C<sub>2</sub>-C<sub>5</sub>-alkenoxy,

R<sup>2</sup> is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl or C<sub>2</sub>-C<sub>5</sub>-haloalkenyl,

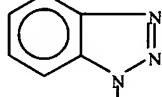
R<sup>3</sup> is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl or C<sub>2</sub>-C<sub>5</sub>-haloalkenyl,

15 R<sup>4</sup> is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl or C<sub>2</sub>-C<sub>5</sub>-haloalkenyl, or

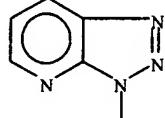
the moiety represented below by P, Q, S or T.



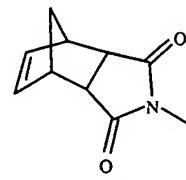
(P)



(Q)

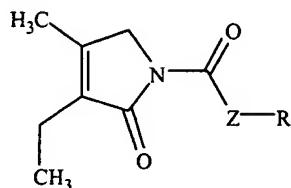


(S)



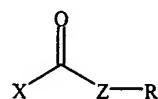
(T)

20 2) A process for the preparation of a compound of formula 3,



Formula 3

comprising reacting 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2,



**Formula 2**

5

wherein,

X is halogen, nitroaryl or haloaryl,

Z is O, S or NY, wherein Y is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl, aryl or aralkyl, and

R is aryl or heteroaryl, where aryl or heteroaryl radical is unsubstituted or substituted by one or more radicals from the group consisting of nitro, halogen, cyano, azido, haloalkyl, CO-R<sup>1</sup>, SR<sup>2</sup>, SO-R<sup>3</sup> and SO<sub>2</sub>-R<sup>4</sup>,

10

R<sup>1</sup> is H, C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-alkoxy or C<sub>2</sub>-C<sub>5</sub>-alkenoxy,

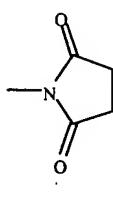
R<sup>2</sup> is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl or C<sub>2</sub>-C<sub>5</sub>-haloalkenyl,

15

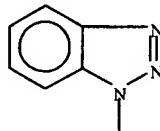
R<sup>3</sup> is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl or C<sub>2</sub>-C<sub>5</sub>-haloalkenyl,

R<sup>4</sup> is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl or C<sub>2</sub>-C<sub>5</sub>-haloalkenyl, or

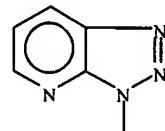
the moiety represented below by P, Q, S or T.



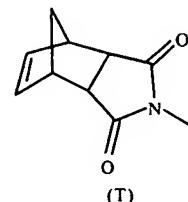
(P)



(Q)



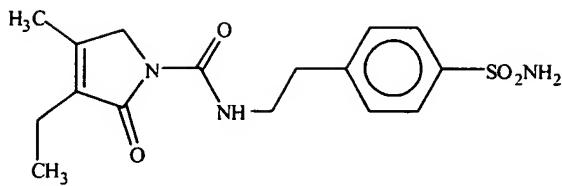
(S)



(T)

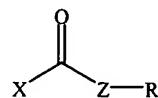
20

3) A process for the preparation of a compound of formula 4,

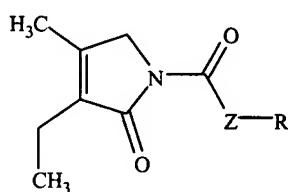
**Formula 4**

comprising,

10 a) reacting 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2,

**Formula 2**

to obtain a compound of formula 3,

**Formula 3**

15 b) reacting a compound of formula 3 with 4-(2-Aminoethyl)benzenesulfonamide to obtain 4-[2-(3-Ethyl-4-methyl-2-carbonyl pyrrolidine amido)ethyl]benzenesulfonamide, a compound of formula 4,

wherein,

X is halogen, nitroaryl or haloaryl,

20 Z is O, S or NY, wherein Y is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl, aryl or aralkyl and R is aryl or heteroaryl, where aryl or heteroaryl radical is unsubstituted or substituted by one or more radicals from the group consisting of nitro, halogen, cyano, azido, haloalkyl, CO-R<sup>1</sup>, SR<sup>2</sup>, SO-R<sup>3</sup> and SO<sub>2</sub>-R<sup>4</sup>,

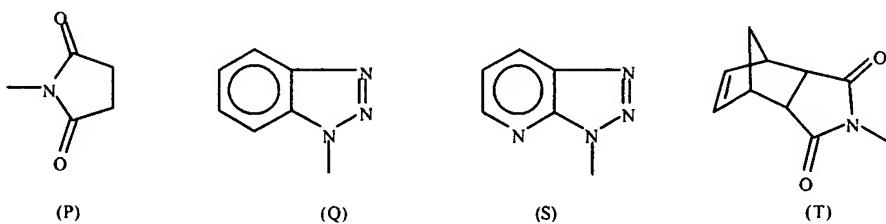
R<sup>1</sup> is H, C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-alkoxy or C<sub>2</sub>-C<sub>5</sub>-alkenoxy,

R<sup>2</sup> is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl or C<sub>2</sub>-C<sub>5</sub>-haloalkenyl,

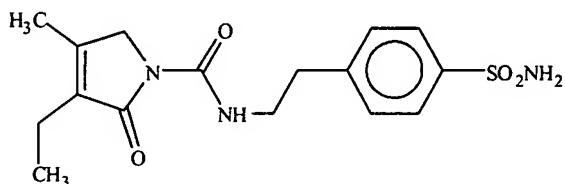
$R^3$  is  $C_1$ - $C_5$ -alkyl,  $C_2$ - $C_5$ -alkenyl,  $C_2$ - $C_5$ -alkynyl,  $C_1$ - $C_5$ -haloalkyl or  $C_2$ - $C_5$ -haloalkenyl,

$R^4$  is  $C_1$ - $C_5$ -alkyl,  $C_2$ - $C_5$ -alkenyl,  $C_2$ - $C_5$ -alkynyl,  $C_1$ - $C_5$ -haloalkyl or  $C_2$ - $C_5$ -haloalkenyl, or

5 the moiety represented below by P, Q, S or T.



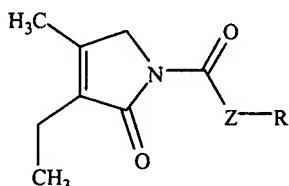
4) A process for the preparation of a compound of formula 4,



10

### Formula 4

comprising reacting a compound of formula 3



### Formula 3

with 4-(2-Aminoethyl)benzene sulfonamide to obtain 4-[2-(3-Ethyl-4-methyl-2-carbonyl

15 pyrrolidine amido)ethyl]benzene sulfonamide, a compound of formula 4,

wherein,

Z is O, S or NY, wherein Y is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl, aryl or aralkyl and R is aryl or heteroaryl, where aryl or heteroaryl radical is unsubstituted or substituted by one or more radicals from the group consisting of nitro, halogen, cyano, azido, haloalkyl, CO-R<sup>1</sup>, SR<sup>2</sup>, SO-R<sup>3</sup> and SO<sub>2</sub>-R<sup>4</sup>.

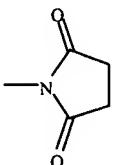
$R^1$  is H,  $C_1$ - $C_5$ -alkyl,  $C_2$ - $C_5$ -alkenyl,  $C_2$ - $C_5$ -alkynyl,  $C_1$ - $C_5$ -alkoxy or  $C_2$ - $C_5$ -alkenoxy,

$R^2$  is  $C_1$ - $C_5$ -alkyl,  $C_2$ - $C_5$ -alkenyl,  $C_2$ - $C_5$ -alkynyl,  $C_1$ - $C_5$ -haloalkyl or  $C_2$ - $C_5$ -haloalkenyl,

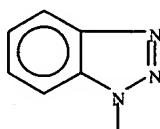
5  $R^3$  is  $C_1$ - $C_5$ -alkyl,  $C_2$ - $C_5$ -alkenyl,  $C_2$ - $C_5$ -alkynyl,  $C_1$ - $C_5$ -haloalkyl or  $C_2$ - $C_5$ -haloalkenyl,

$R^4$  is  $C_1$ - $C_5$ -alkyl,  $C_2$ - $C_5$ -alkenyl,  $C_2$ - $C_5$ -alkynyl,  $C_1$ - $C_5$ -haloalkyl or  $C_2$ - $C_5$ -haloalkenyl, or

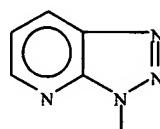
the moiety represented below by P, Q, S or T.



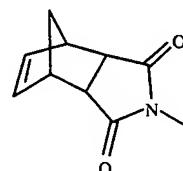
(P)



(Q)



(S)



(T)

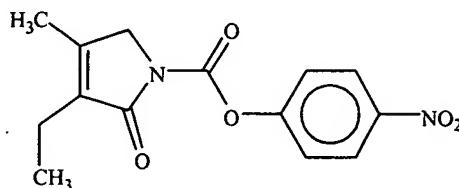
10

5) The process as claimed in claim 4 wherein the compound of formula 4 is further reacted with *trans*-4-methylcyclohexyl isocyanate to obtain the compound of formula 1.

15 6) The process as claimed in claim 1, 2 or 3 wherein the reaction of 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2, is carried out in presence of an organic base.

7) The process as claimed in claim 1, 2 or 3 wherein 3-Ethyl-4-methyl-3-pyrrolidin-2-one is reacted with the compound of formula 2, wherein Z is O and R is 4-nitrophenyl,

20

**Formula 3a**

to obtain a compound of formula 3a.

8) The process as claimed in claim 1 comprising,

a) reacting 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2, wherein Z is O and R is 4-nitrophenyl, to obtain a compound of formula 3a,

b) reacting the compound of formula 3a with 4-(2-Aminoethyl)benzene sulfonamide to obtain 4-[2-(3-Ethyl-4-methyl-2-carbonyl pyrrolidine amido)ethyl]benzene sulfonamide, a compound of formula 4,

5 c) and further reacting the compound of formula 4 with *trans*-4-methylcyclohexyl isocyanate to obtain the compound of formula 1.

9) The process as claimed in claim 3 comprising,

10 a) reacting 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2, wherein Z is O and R is 4-nitrophenyl, to obtain a compound of formula 3a,

b) reacting the compound of formula 3a with 4-(2-Aminoethyl)benzene sulfonamide to obtain 4-[2-(3-Ethyl-4-methyl-2-carbonyl pyrrolidine amido)ethyl]benzene sulfonamide, a compound of formula 4.

15 10) The process as claimed in claim 4 comprising reacting a compound of formula 3, wherein Z is O and R is 4-nitrophenyl with 4-(2-Aminoethyl)benzene sulfonamide to obtain 4-[2-(3-Ethyl-4-methyl-2-carbonyl pyrrolidine amido)ethyl]benzene sulfonamide, a compound of formula 4.

11) The process as claimed in claim 5, wherein the compound of formula 4 is prepared by a process comprising reacting a compound of formula 3, wherein Z is O and R is 4-nitrophenyl, with 4-(2-Aminoethyl)benzene sulfonamide to obtain 4-[2-(3-Ethyl-4-methyl-2-carbonyl pyrrolidine amido)ethyl]benzene sulfonamide, a compound of formula 4.

20 12) The process as claimed in claim 1, 2 or 3 wherein the reaction of 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2, is carried out in presence of an organic base selected from the group consisting of 4-dimethylaminopyridine; 4-pyrrolidinopyridine; diisopropylethylamine, tetramethylguanidine; 1,8-diazabicyclo[5.4.0]undec-7-ene; 1,5-diazabicyclo [4.3.0] non-5-ene; 2,6-lutidine and picolines.

25

13) The process as claimed in claim 1, 2 or 3 wherein the reaction of 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2 is carried out in presence of an acid scavenger compound.

14) The process as claimed in claim 1, 2 or 3 wherein the reaction of 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2 is carried out in presence of an acid scavenger compound selected from the group consisting of trialkylamines, pyridine, sodium carbonate and potassium carbonate.

15) The process as claimed in claim 1, 2 or 3 wherein the reaction of 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2 is carried out in presence of an acid scavenger compound characterised in that the acid scavenger compound is triethylamine.

16) The process as claimed in claim 1, 2 or 3 wherein the reaction of 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2 is carried out in presence of an organic base and an acid scavenger compound, characterised in that the organic base is 4-dimethylaminopyridine and the acid scavenger compound is triethylamine.

17) The process as claimed in claim 1, 2 or 3 wherein the reaction of 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2 is carried out in presence of a solvent selected from the group consisting of aliphatic or aromatic hydrocarbons, ethers, nitriles and amides.

18) The process as claimed in claim 1, 2 or 3 wherein the reaction of 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2 is carried out in a chlorinated hydrocarbon solvent.

19) The process as claimed in claim 1, 2 or 3 wherein the reaction of 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2 is carried out in dichloromethane.

20) The process as claimed in claim 1, 2 or 3 wherein the reaction of 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2 is carried out at a temperature between the range of about 0°C to about 35°C for about 8 to about 15 hours.

21) The process as claimed in claim 1, 3 or 4 wherein the reaction of a compound of formula 3 with 4-(2-Aminoethyl)benzene sulfonamide to obtain 4-[2-(3-Ethyl-4-methyl-2-carbonyl pyrrolidine amido)ethyl]benzene sulfonamide, a compound of formula 4, is carried out in the presence of a solvent selected from the group consisting of aliphatic or aromatic hydrocarbons, ketones, nitriles and amides.

5

22) The process as claimed in claim 10 wherein the reaction is carried out in acetone.

23) The process as claimed in claim 1, 3 or 4 wherein the reaction of a compound of formula 3 with 4-(2-Aminoethyl)benzene sulfonamide to obtain 4-[2-(3-Ethyl-4-methyl-2-carbonyl pyrrolidine amido)ethyl]benzene sulfonamide, a compound of formula 4, is carried out at a temperature between the range of about 35°C to 10 about 80°C for about 0.5 to about 20 hours.

10

24) The process as claimed in claim 2, comprising reacting 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2, wherein X is Cl, Z is O and R is 4-nitrophenyl, to obtain 3-Ethyl-4-methyl-2,5-dihydro-N-(4-nitrophenyloxy carbonyl)-pyrrole-2-one, a compound of formula 3a, having purity of greater than 15 99%.

15

25) The process as claimed in claim 24, wherein the compound of formula 3a is further reacted with 4-(2-Aminoethyl)benzene sulfonamide to obtain 4-[2-(3-Ethyl-4-methyl-2-carbonyl pyrrolidine amido)ethyl]benzene sulfonamide, a compound of formula 4 having purity of greater than 99%.

20

26) The process as claimed in claim 1 comprising,

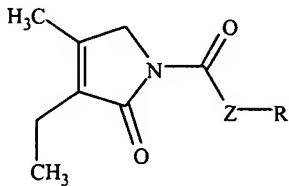
25

a) reacting 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2, wherein X is Cl, Z is O and R is 4-nitrophenyl, to obtain a compound of formula 3a,

b) reacting the compound of formula 3a with 4-(2-Aminoethyl)benzene sulfonamide to obtain 4-[2-(3-Ethyl-4-methyl-2-carbonyl pyrrolidine amido)ethyl]benzene sulfonamide, a compound of formula 4,

c) and further reacting the compound of formula 4 with *trans*-4-methylcyclohexyl isocyanate to obtain the compound of formula 1 having 30 purity of greater than 99%.

27) The intermediate compound of formula 3,



5

**Formula 3**

wherein,

Z is O, S or NY, wherein Y is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl, aryl or aralkyl, and R is aryl or heteroaryl, where aryl or heteroaryl radical is unsubstituted or substituted by one or more radicals from the group consisting of nitro, halogen, cyano, azido, haloalkyl, CO-R<sup>1</sup>, SR<sup>2</sup>, SO-R<sup>3</sup> and SO<sub>2</sub>-R<sup>4</sup>,

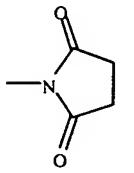
10 R<sup>1</sup> is H, C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-alkoxy or C<sub>2</sub>-C<sub>5</sub>-alkenoxy,

R<sup>2</sup> is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl or C<sub>2</sub>-C<sub>5</sub>-haloalkenyl,

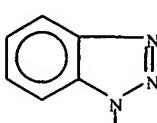
15 R<sup>3</sup> is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl or C<sub>2</sub>-C<sub>5</sub>-haloalkenyl,

R<sup>4</sup> is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl or C<sub>2</sub>-C<sub>5</sub>-haloalkenyl, or

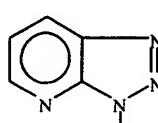
the moiety represented below by P, Q, S or T.



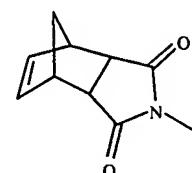
(P)



(Q)



(S)



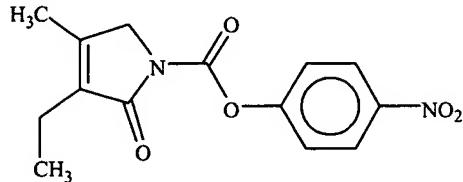
(T)

20

28) The intermediate compound of formula 3, as claimed in claim 27 wherein Z is O and R is aryl or the moiety represented by (P), (Q), (S) or (T), characterised in that aryl is phenyl substituted with one or more radicals selected from nitro, halo, cyano, 4-trifluoroalkyl, 2,4-bis(trifluoroalkyl) or 2,6-bis(trifluoroalkyl).

29) The intermediate compound of formula 3, as claimed in claim 27, wherein Z is O and R is selected from phenyl substituted with 4-nitro, 2,4-dinitro, 2,6-dinitro, 4-halo, 2,4-dihalo, 2,6-dihalo, 4-trifluoromethyl, 2,4-bis(trifluoromethyl) or 2,6-bis(trifluoromethyl).

5 30) The intermediate compound of formula 3a.



**Formula 3a**

31) The intermediate compound of formula 3, as claimed in claim 27, wherein Z is O

10 and R is represented by the moiety (P), (Q), (S) or (T).